at that then, and I'll give you the copies of PMA.

CHAIRMAN WHALEN: Are there any questions?

No response.)

CHAIRMAN WHALEN: We'll, just for planning purposes, have one more speaker and then we'll break for lunch and reassemble after for the conclusion of the public speakers.

Before lunch, we'll have Ms. Ann Fonffa from the Annie Appleseed Project. She's not here.

Ms. Margaret Volpe from Y-ME.

MS. VOLPE: Thank you for allowing me to present this statement to the advisory panel.

My name is Margaret Volpe. I am a breast cancer survivor and a breast implant recipient. I have no financial ties to manufacturers or health care providers, and I'm not being reimbursed for my appearance here today.

I am a volunteer representing Y-ME national breast cancer organization. We are based in Chicago and have chapters nationwide. We believe that no one should face breast cancer alone. So we operate a 24 hour national 1-800 number, hot line in Spanish

and in English, and provide peer support and educational programs.

Y-ME is committed to providing support and accurate information to empower individuals touched by breast cancer so that they can select the most appropriate options for themselves in conjunction with their health care provider.

When I was diagnosed with breast cancer in 1995, I faced the fears, anxiety and depression common to those diagnosed with a life threatening illness. Because of the size and location of my tumor, I had to have a mastectomy.

I chose to have a tissue expander inserted into my chest when I had my mastectomy. This was followed by an implant placed under the pectoral muscle in February 1996 once I'd completed chemotherapy.

It was very important to me to have reconstruction, not have to worry about how clothes would fit, to feel whole again, for my family and me not to be constantly reminded of my breast cancer, and to get on with my life.

And I have had no problems or complications with my implant since my surgery.

Now, let me tell you why I selected an implant for my reconstruction. Now, I know I have ample tissue on my abdomen to be eligible for tram flap reconstruction. However, I knew I didn't want to have to endure the major abdominal surgery and painful recovery period required for the surgery, and I also wanted to keep those muscles intact.

I have several friends who did not have this option at all. They were told they were too thin to have the needed tissue for the tram reconstruction. Even the latissimus dorsi, or back flap reconstruction, usually requires an implant.

By doing nothing and settling on an external prosthesis, my friends and I would be reminded daily of the mutilation to our breast. Each woman who has had a mastectomy must be allowed to pursue the best option for her, including breast implants.

At present, if a woman has had tram reconstruction on one breast, she is unable to have a

second tram reconstruction at a later date if she should develop cancer in the other breast. It is imperative that we continue to have a choice, and for many of us, implants are the only option we have.

Y-ME and I believe the availability of saline implants is very important to women who face breast cancer. It is the only uncomplicated option left for women who desire an implant as part of their breast reconstruction after the FDA restriction in 1992.

It was very difficult for me to get the textured reverse, double lumen implant I received in 1996 because of FDA restrictions that required me to be in a clinical trial. I am on a patient registry.

In addition, the informed consent I signed in order to participate in the implant study was much more lengthy and detailed than the informed consent I signed to have the potentially deadly stem cell rescue in a clinical trial at Johns Hopkins.

This panel must stick to the science when evaluating saline breast implants. Do not allow yourselves to get diverted and sidetracked by special

interests that may have litigation more on their minds than health issues.

The National Academy of Sciences' Institute of Medicine report has been issued, and the science is clear. The IOM conducted an exhaustive and definitive review of all existing research and found that there is no evidence that silicone breast implants cause cancer or disease.

This report also found the same result for saline breast implants. The U.S. court's National Science Panel and several European government scientific panels issued similar findings. W-ME emphasizes the need for a wide range of treatment options as each woman, each woman must be able to choose the option that best fulfills her needs.

One of W-ME's main messages to women and families seeking our help is to fully understand the risk and benefits of any medical choice, including the usual surgical risks. We have worked with FDA to produce accurate information and used the FDA breast implant information booklet when counseling women.

And when it comes to the implant itself,

women should understand that no medical device lasts forever. Shunts, heart pacemakers, even artificial knees and joints have an expected life span and possible local complications.

And women should be aware of potential rupture and the need for replacement. Adequate informed consent is a key part of the process. Doctors should discuss the issues of risk and benefit in detail with their patients.

Saline implants do have a silicone shell, but from the exhaustive research on silicone implants, pointed out by the IOM report, we also know that there is no convincing evidence that silicone produces an immunologic response. The IOM report states that such diseases or conditions are no more common in women with breast implants than in women without breast implants.

In closing, W-ME would like to work with FDA on informed consent and labeling issues that will be required if the FDA approves the PMAs. I urge the committee to act based on the science alone.

Breast cancer is a devastating disease.

In the effort to resume our lives, breast cancer survivors have the right to select appropriate and effective medical therapies or devices.

Thank you very much.

CHAIRMAN WHALEN: Thank you.

Ms. Volpe, I perhaps didn't hear it. Did you at the beginning identify any financial relationships of your organization?

MS. VOLPE: As I said, I'm a volunteer.

CHAIRMAN WHALEN: And W-ME receives no funding from any manufacturers of implants?

MS. VOLPE: I believe that they have funding provided in the past by some, and our funding is public knowledge and can be --

CHAIRMAN WHALEN: Right, but we do ask each of the speakers to identify that so that if there can be any potential bias, those four questions need to be answered, and one of those would be if your organization receives funding from any manufacturers. So that is, indeed, the case.

MS. VOLPE: I believe in the past it has been.

CHAIRMAN WHALEN: Thank you.

Are there any questions of the panel members?

(No response.)

CHAIRMAN WHALEN: Thank you.

As I stated, we're going to break for lunch. I have right now about 12:05, and we'll take 45 minutes. So please reassemble at a time sufficient so that we can begin business at ten minutes to one.

(Whereupon, at 12:03 p.m., the meeting was recessed for lunch, to reconvene at 12:50 p.m., the same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(12:56 p.m.)

CHAIRMAN WHALEN: If everyone could take their seats, please, we'll try to resume. If everyone could please be seated, we'll resume the continuing public comments from consumer groups and consumer information providers.

And the next identified speaker if she's present is Ms. Stansell, who is here from the United Silicone Survivors of the World.

MS. STANSELL: I'm Anne Stansell from New Mexico.

The question is who's paying for this trip. My husband and I are.

Now, I need to explain something. We both work only part time due to health reasons. My trip all the way from New Mexico costs about $1,000. That's a lot of money for a couple that only makes about 24,000 in a year. I'm stating these figures to let you know how very important it is for all of us to tell you that we are sick from breast implants. So please take this seriously as we do.

The answer to the next question is -- are you a party to a pending lawsuit? -- I am a claimant in the Dow bankruptcy court. Dow is offering a settlement, which means I will probably end up getting $1.98, and my lawyer will get two thirds of that.

The answer to the other questions is no.

I'm speaking to you as a leader of a group of women in New Mexico in a similar situation. There are some of their photographs so they can be here in a way.

Ninety percent of the women in our group in New Mexico are cancer survivors. Many have saline filled silicone shell breast implants. None of us had all the facts when we made the decision to get the breast implants. None of us realized we had a choice.

It was presented to me as all part of the treatments. My doctor said, "You have cancer. You need mastectomies, radiation, and breast implants." There was no discussion. No facts were presented to me other than breast implants are perfectly safe and will last forever. This experience is commonly shared by others in our group.

If they should ever leak, we'll just replace them, the doctor said, as if it's as easy as changing hair styles.

No one told me that breast implants rupture often. No one told me about infections. No one warned me about other complications causing a need for 14 more surgeries or procedures. No one warned us that saline would get rancid and grow fungus. No one warned us about capsular contracture until a plastic surgeon pounded on our tender chests with both fists.

If I had had all the facts, I would never have chosen breast implants, "chosen" being the key word. It should be presented to a cancer patient and all others as a choice, and one can only make an intelligent choice if one has all the facts.

Furthermore, the group of cancer surviving women I represent here before you wants me to tell you that breast implants are not medically necessary. We did not need breast implants to get over cancer. Implants are not life saving devices. They are life damaging devices.

We have been robbed of our survival to

live a healthy life to a mature old age. We should have been warned by the FDA that they knew nothing about the device being surgically implanted. I guess there is some warning on a thing called "package insert."

Now, think about it a moment. "Package insert." It is wrapped inside the sterile package. It is not opened until the patient is under anesthesia. I don't read well under anesthesia.

In closing, we need to know when is enough. ASPRS (phonetic) tells us that 80,000 women of child bearing age received saline filled silicone shell breast implants in 1999. Many will file Medwatch forms of adverse reactions as many of us already have.

What number is enough? When does it stop? Is it ten percent, 20 percent? What's it going to take? Is it 50 percent?

Even ten percent is too much.

I charge the FDA to validate now the clinical trials the manufacturers have submitted. Check into selected patient follow-up. Check into

patient intimidation by giving up their rights to sue.

Thank you.

I give the remainder of my time to Dr. Blais.

CHAIRMAN WHALEN: Are there any questions?

(No response.)

CHAIRMAN WHALEN: Thank you.

Is Dr. Blais here? I have been told that he is not here.

PARTICIPANT: He's here.

CHAIRMAN WHALEN: All right. While we see if he'll arrive, are any of the following here? Ms. -- unfortunately we had no timer, but it was about five minutes left -- Ms. Fonffa, Ms. Mullen, Ms. Williams. None of those are available? Ma'am?

PARTICIPANT: (Inaudible.)

CHAIRMAN WHALEN: Yes. Actually that's going to be a little bit delayed from 12:50. We're following sequence, but you will be called.

Is Dr. Puckett available?

DR. PUCKETT: Good afternoon. I'm Dr. Lin Puckett, professor and head of the Division of Plastic

Surgery at the University of Missouri Health Sciences Center in Columbia, Missouri. I'm also President of the American Society of Plastic Surgeons.

The Educational Foundation of the ASPS has received undirected research funds from both Mentor and McGhan. These have been used for implant research. Both of them are also exhibitors at our national meeting, along with about 350 other exhibitors.

My travel and hotel expenses are being paid by the American Society of Plastic Surgeons. I have no ties to the manufacturers myself. I'm not involved in any lawsuit involving breast implants. As a part of my broad based practice of plastic surgery in the academic environment, I perform breast implant surgery both for reconstructive and cosmetic reasons. I, therefore, derive a portion of my income from this type of surgery.

The ASPS represents 5,000 Board certified plastic surgeons in the United States and Canada. It is the largest organization in the world of surgeons certified by the American Board of Plastic Surgery.

Our members have provided care for most of the more than one and a half million women who have chosen breast implant surgery over the past 30-plus years.

As physicians, we know the women who have benefitted from breast implant surgery, but who may be uncomfortable speaking about this very personal subject in this public forum. We are their advocates.

The FDA determined in 1992 that there is public health need for silicone filled breast implants. Women's request for silicone or saline filled implants dropped off temporarily due to the concerns of the early 1990s. However, since 1995, we've seen a resurgence of interest in and demand for breast implant surgery.

The majority of breast implant procedures performed today is the silicone inflatable shell or saline filled breast implant due to the clinical study restrictions on silicone gel filled implants. Today only three companies market the saline implant in the United States.

Important research data has emerged in recent years on both gel and saline filled implants.

Because the outside envelope that is used for both gel filled and saline filled implants is a silicone elastomer shell, the study findings on gel implants to a great extent also apply to saline filled implants.

In 1997, the prestigious Institute of Medicine of the National Academy of Sciences undertook a major study of silicone breast implants funded in part by the FDA and referred to several times this morning. The IOM's key findings released in June of '99 concluded that silicone implants do not cause major disease. Breast feeding does not pose a health threat to infants. Silicone implants do not harm the developing fetus. Radiation does not hurt implants and vice versa, and that breast implants have improved over time, reducing local complications.

It further reported that implants do not weaken the immune system and that, in general, silicone as present breast implants is safe.

The findings of this landmark study are reassuring for women and physicians. They confirm the positive clinical experience of plastic surgeons over the years and the high level of satisfaction reported

by women with implants.

The study also recognizes the problems that can occur in women with implants. These include the possible need to replace implants, local complications, and the potential need for additional surgery.

These factors are relevant for both silicone gel filled implants and saline filled implants.

The latest data on these potential problems specific to saline filled breast implants will be presented subsequently at this hearing. Data from a recent University of Minnesota multi-center, retrospective study of 450 patients with saline filled breast implants with a minimum follow-up of ten years shows a deflation rate of 5.8 percent for implant models currently in use. This would be a failure rate of less than one percent per year, and this is in contrast to the interpretation of these statistics quoted earlier today.

Deflation of a saline filled breast implant is generally harmless but carries the risk

associated with additional surgery for replacement. While these risks are not insignificant, they must be viewed in the context of the patient's overall risk-to-benefit ratio.

The Minnesota study, designed in consultation with the FDA, found that patient satisfaction with saline filled breast implants is extremely high. Ninety-three percent of patients, most of whom received implants for cosmetic breast enlargement, reported that they were satisfied or very satisfied with their surgery. Ninety-six percent said they would make the same choice again.

Extensive scientific studies today document the safety of silicone implants and the high level of patient satisfaction. Much of the past controversy surrounding breast implants has focused on claims of a link between silicone and autoimmune diseases.

While a saline filled breast implant contains only sterile saltwater solution, its shell is made of a silicone elastomer. As recently as August of '99, the FDA stated in the Federal Register that no

definitive link between immunologic or connective tissue disorders and saline filled breast implants has been found.

Further, after comprehensive evaluation of the evidence for association of silicone breast implants with human health conditions, the Institute of Medicine concluded in June of '99 that there is no definitive evidence linking breast implants to cancer, immunologic diseases, neurological problems, or other systemic diseases.

What then constitutes the major risks associated with saline filled breast implants? Besides deflation, there is the risk of capsular contracture, tightening of the natural scar tissue that forms around the implant, and it can cause breast firmness.

The occurrence of capsular contracture is unpredictable, and if severe may require corrective surgery. In the Minnesota study, only four percent of patients rated their reconstructed or augmented breasts as hard, while 24.5 percent said their breasts were slightly or moderately firm.

While the ideal of implant surgery is a soft, natural feeling breast, some degree of firmness may be well tolerated by the patients, as evidenced by the high rate of patient satisfaction recorded in that same Minnesota study.

A concern associated with breast implants is the possibility that the devices may interfere with the early detection of breast cancer. Mammography of the implanted breast requires special techniques and additional X-ray views. However, recently published University of Southern California study of breast cancer diagnosis and survival among 3,182 women with breast implants in Los Angeles County showed the stage of cancer diagnosis was virtually identical to that of all breast cancer patients in L.A. County.

In addition, the five year survival rate was consistent with rats established by the National Cancer Institute. There is no evidence that implants cause breast cancer. In fact, two major studies have shown a lower than expected incidence of breast cancer in women with breast implants.

Plastic surgeons have seen first hand how

a woman's quality of life can be tremendously improved by these devices. Every plastic surgeon can provide numerous stories about women whose self-confidence flourished after augmentation mammoplasty.

We also know first hand of many mastectomy patients who have expressed that they have only felt themselves to be recovered from their breast cancer experience when their bodies were restored with breast reconstruction.

The responsibility that our patients bestow on us as plastic surgeons when we perform breast implant surgery is taken very seriously. We believe that women should be fully informed of the potential risks and benefits of implants and should have the right to choose implants to restore their breasts following cancer, trauma, or deformity, or to achieve a satisfying breast appearance through augmentation.

Women who would wish to have breast implant surgery are often made to feel that the procedure is frivolous and poses unnecessary risk. Yet studies have confirmed that most of these women

experience improvements in self-esteem and body image and quality of life.

We must also remember that there is no alternative currently available to breast implants. Autogenous procedures to reconstruct the breast require extensive surgery and may not be an option or are impractical for many patients. Autologous tissue transfer for breast enlargement could not be justified.

We believe that breast implants fill a significant health need, and we will continue to work to insure that women have access to this procedure and the right to make their own informed choice to proceed or not. The research findings of the recent years have significantly restored women's faith in breast implant safety and efficacy.

Thank you.

CHAIRMAN WHALEN: Thank you, Dr. Puckett.

Are there any questions from the panelists?

(No response.)

CHAIRMAN WHALEN: Thank you, sir.

DR. PUCKETT: Thanks.

CHAIRMAN WHALEN: Before proceeding to the next speaker, I'm told that one of the speakers who could not be here, Ms. Mullen from the Women's Information Network against Breast Cancer, that Ms. Brinkman will read a statement that was submitted by her.

MS. BRINKMAN: Thank you. I was just given this. So this in no way reflects any bias on my part.

This is from Elizabeth Mullen --

CHAIRMAN WHALEN: As you're starting, do know of any financial arrangement that that organization has?

MS. BRINKMAN: I don't even know who she is. So --

CHAIRMAN WHALEN: Thank you.

MS. BRINKMAN: I do not.

It's from Elizabeth Mullen, President, CEO of Women's Information Network Against Breast Cancer, written testimony.

I very much appreciate the opportunity to

submit my written testimony to you for consideration. I had hoped to be here today in person, but was unable to make the trip from California due to circumstances beyond my control. My remarks will adhere to the ten minute oral testimony limit.

I am founder, President and CEO of the national, nonprofit organization Women's Information Network Against Breast Cancer. The acronym is WINABC.

As such, I am representing WINABC for the purposes of this testimony and would like to communicate from the perspective not only of an advocate, but also as a breast cancer survivor who has had a mastectomy and immediate post reconstruction latissimus dorsi with a saline filled breast implant, and finally as a woman who cares deeply about the issue being addressed today and throughout this week: the availability of saline filled implants and a woman's right to choose.

Oh, she goes on to say at the bottom, "And I have in no way been reimbursed for addressing this panel." She says her organization has received grants from a few pharmaceutical companies, Glaxo Wellcome.

"I am not a witness or party to a pending lawsuit, and my income is not derived from breast implants."

My perspective as a breast cancer survivor and as a woman. I was diagnosed with breast cancer nearly seven and a half years ago at the age of 33. Judging from the size of my tumor, my physicians estimated that the malignancy had been there for seven to ten years.

Breast cancer had not been on my physicians' radar screens, nor had it been on mine. I quite simply did not fit the profit of a woman with breast cancer, or so it seemed.

Wrong assumptions had been made regarding my health status, and as a result, when I was finally diagnosed with breast cancer, my treatment options were limited. Due to the size and location of the tumor in my breast and the size of my breast in relation to the size of the tumor, I opted for breast conserving surgery. I would have, in essence, ended up with a partial mastectomy.

Due to these factors, there was consensus that a mastectomy was my best surgical option. I was,

to say the least, fraught with sadness and fear over the prospect of losing my breast, facing chemotherapy, and the prospect of dying within two to three years. I was overwhelmed, confused, and numb. Being misdiagnosed for several years robbed me of some very important choices.

I was fortunate that my surgical oncologist called in a plastic and reconstructive surgeon for my initial surgical consult. My first glimpse of hope in the painful days following my diagnosis was learning that breast reconstruction was an option for me.

The prospect for my waking up after surgery without a breast was devastating to me. When my plastic surgeon explained that I could have an immediate breast reconstruction, my outlook began to improve, and I began to regain my strength of spirit.

Because of many factors, I was not a good candidate for a tram flap reconstruction. So reconstruction with an implant was my best option, my only option, as it turned out.

I remember making love with my husband for

the last time before my mastectomy and reconstruction. It was so bittersweet. What would it be like after surgery? There were so many unknowns.

I share this with you because the personal and intimate perspectives of all women all too often get bypassed in forums such as this.

Just as the science is critical, as you consider the efficacy of saline filled breast implants, so, too, is the conscience, body, mind, and spirit of individuals who choose to have surgery with implants, be it for cosmetic augmentation or breast reconstruction.

How do you quantify hope, self-esteem, body image, sexuality? How do you hope self-esteem and a positive self-image impact of a 33 year old woman fighting for her life after breast cancer surgery, or as a teenage young lady with a chest defect following reconstruction to correct the anomaly, or a 50 year old woman who has never been comfortable with her AA size breast, who following breast augmentation experiences a new sense of womanhood?

I urge you to keep this human and humane outlook in mind.

I am blessed to be married to the one and only true love of my life, my high school sweetheart. I have known Ken since I was 16 years old. We always knew that we would get married, and for years we had the name of our first child all picked out, Semantha Ann Mullen, SAM for short, SAM, a daughter we never knew. Because of my chemotherapy protocol, Ken and I will never be able to have children together. Although we never had been warned about it, chemotherapy threw me into permanent menopause. I never had a choice in the matter.

Choice, one word that means so much. When a woman faces the diagnosis of breast cancer, she experiences a range of feelings that often include loss of control and grief over the possible loss of a breast.

But the good news is women have choices, including important choices in breast reconstruction. Limiting these choices by limiting or eliminating the availability of saline filled breast implants would be

a tragic and devastating blow to women.

What's at stake here today and throughout this week is a woman's right to choose, and here is where my perspective shifts from that of an individual patient and a women who has experienced first hand the positive impact of breast reconstruction with an implant to that of a woman's health advocate, working to insure equal access to quality health care for individuals.

My perspective as an advocate and CEO of WIN Against Breast Cancer: "knowledge is the antidote to fear."

I founded the WIN Against Breast Cancer following my own experiences with breast cancer. The WIN organization was established to provide patients with the information and resources that they need to make to make confident and informed health care decisions. We place particular focus on helping women and men understand their treatment options and empowering individuals with the even knowledge about their choices and health care.

Choice and knowledge, informed decision

making are at the core of WIN's organization, mission and goals. WINABC strives to provide individuals from all cultural and socioeconomic backgrounds with responsible, unbiased information about breast health, breast cancer, and personal health responsibility.

WIN was also founded to be a catalyst for change in partnership and to serve as a conduit by which individuals and organizations can be linked to one another in areas of common interest and purpose.

I will leave the science to the scientists and the clinicians, but I'd like to highlight a few key points regarding the great implant debate.

The device. Breast implants have been studied for 20 years and have been under intense scrutiny for a large portion of that time.

The science is sound and ongoing.

Product information. I have been able to see first hand and experience first hand the improvements that have been made in the product development with respect to saline filled breast implants over the years.

I started off this portion of my remarks

with a quote about knowledge, another important development with respect to the devices under consideration by this panel: saline filled breast implants. Is the improvement in provider and consumer education? The bottom line: we fear what we do not know and understand.

As an advocate who has worked with hundreds of women over the years and dozens of providers, I can report first hand that what I referred to is myth conceptions are oftentimes tragic barriers to women seeking life saving breast cancer screening and treatment services.

I cannot count the times women have called our organization following a sound byte on the news about, quote, the dangers of implants or the, quote, deadly side effects of Tamoxifen or the, quote, long term, ineffectiveness of lumpectomies.

Hype destroys hope. Misinformation leads to disintegration of health. Overstated? Unfortunately not.

Women often fear the prospect of losing their breast to cancer more than chemotherapy or the

disease itself. The fear is a barrier to women examining herself or seeking screening and treatment services. Oftentimes and tragically, women will ignore a palpable lump for years and present in the clinic with open sores on their breast in late stage disease because of the fear of losing a breast.

Many women do not know that breast reconstruction, immediate or delayed, is an option for them. When women fully understand their options, the benefits and risks, and are given access to peer support, second opinions, and culturally sensitive, linguistically appropriate, educational materials, they are more likely to make intelligent, competent treatment decisions and more likely will comply with treatment.

And when physicians are made aware of these issues and barriers, they can more effectively communicate with their patients and improve outcomes.

I will never forget the day when I was making rounds with a surgical oncologist. I was with him as he delivered a breast cancer diagnosis to a Latino patient. The patient clearly needed a

mastectomy, but because of a variety of reasons refused surgery.

On her second visit to the clinic to again discuss options, her surgeon called me in and told the patient that I had a mastectomy and reconstruction. We showed her my reconstruction, explained the procedure. The unknown of surgical outcomes was now a known. She could envision the end result of a breast reconstruction and knowledgeably and willingly agree to the surgery.

Her choice was made real and tangible. She chose treatment over fear and flight from treatment. The choice, her right to choose, saved her life. She was the rule, not the exception.

In closing, I am going back to the beginning of my remarks. I was given my breast cancer diagnosis over the telephone. The entire conversation lasted no more than three minutes, three minutes frozen in time that forever changed my life. It's a time frame that makes me uneasy not because of a bad memory, but because every three minutes another woman is diagnosed with breast cancer.

Every day women are seeking breast cancer treatment options that include reconstruction with saline filled breast implants, often their best and only -- their only reconstructive option, an option that can result in a new lease on life at a time when life seems so fragile and precarious, a choice that means hope, healing, and vitality to the all too many women confronted with a diagnosis of breast cancer every day in this country and around the world.

I will close with a favorite scripture of mine. "Where there is no vision people perish."

It is my sincere hope that your vision, insight and wisdom will result in preserving the ability of saline filled breast implants and the opportunity and right for women to choose whether or not to use these devices.

Device? Funny. As I look in the mirror, it's hard for me to consider that my feminine silhouette is attributed to a device. This device, this implant has become a part of me, and I dare say has outlived my original prognosis of two to three years by several years, for which I'm grateful on many

levels. Other women deserve that chance.

Thank you.

CHAIRMAN WHALEN: Thank you for reading that.

Before proceeding to the next speaker, if there's anybody from either FDA or Holiday Inn in the room who has the password to the thermostat and could drop it a couple of degrees, I think we'd all be immensely appreciative.

The other professional society that will be address --

DR. BURKHARDT: I have a question for the chair. May I ask a procedural question at this time?

CHAIRMAN WHALEN: Oh, procedural, yes.

DR. BURKHARDT: Yeah, a procedural question.

We've heard lots of stories, individual stories for and against this whole thing. In our training session last night, the new members had a training session with the FDA. My understanding was that in our deliberations as we sit here, we are precluded by statute from considering these individual

experiences and experiential reports.

CHAIRMAN WHALEN: FDA questions I'll deflect to Dr. Witten.

DR. WITTEN: In terms of when you make a recommendation about reasonable assurance of safety and effectiveness of each of the PMAs, you are to consider the data in the PMA and your scientific knowledge.

DR. BURKHARDT: Period?

DR. WITTEN: Yes.

DR. BURKHARDT: Thank you.

CHAIRMAN WHALEN: The other professional society to address us this afternoon is the American Society for Aesthetic Plastic Surgery represented by Dr. David Sarwer.

DR. SARWER: Good afternoon. My name is Dr. David Sarwer. I'm assistant professor of psychology and psychiatry in surgery at the University of Pennsylvania School of Medicine.

I'm testifying today at the request of the American Society for Aesthetic Plastic Surgery which will reimburse me for my travel expenses to this

hearing. I have in the past received two small grants, one from the American Society of Aesthetic Plastic Surgery and one from the University of Pennsylvania Research Foundation to support my research on the psychological characteristics of breast augmentation patients.

However, I do not derive any salary support from these grants. I am not involved as a witness or party to any pending lawsuit related to breast implants.

Members of panel, I am here today to present information relevant to your consideration of the safety and efficacy of saline filled breast implants. My comments are from a psychological perspective and are based on my expensive -- extensive experience --

(Laughter.)

DR. SARWER: Not so most expensive -- in the area of the psychology of cosmetic surgery.

Over the last five years I have published 21 empirical papers, review articles, book chapters, and discussions on the psychological aspects of

plastic surgery. There articles have appeared in both the plastic surgery and psychological literatures. Many of these papers have focused on cosmetic breast augmentation patients.

In 1999, I served as a chairman of a symposium on cosmetic surgery at the seventh annual Congress of Women's Health and Gender Based Medicine.

Finally, I've recently written a review paper which is currently under editorial review specifically focusing on the psychological aspects of cosmetic breast augmentation surgery.

Therefore, I am uniquely qualified to discuss the psychological issues related to cosmetic breast argumentation.

The popularity of breast augmentation surgery means that internists, obstetrician-gynecologists, and many other women's health care professionals are increasingly called upon to provide appropriate advice and guidance concerning this procedure.

As you are aware, breast augmentation surgery has become increasingly common with women from

a variety of age, racial and socioeconomic groups now seeking the surgery.

Thus, I believe that much greater sensitivity to the psychological issues of breast augmentation is required from the medical community at large.

Over the past 40 years, numerous studies have investigated the psychological issues of breast augmentation patients. The majority of these studies were conducted with women who received silicone gel filled breast implants.

Nevertheless, with the exception of studies which have investigated the surgical complications and satisfaction rates, it may be safe to assume that the psychological motivations of women who have received both silicone filled implants and saline filled implants are similar.

Based on our published reviews of the literature, my colleagues and I believe that there has been a lack of solid data on the psychological characteristics of breast augmentation patients. While a variety of studies have been undertaken, most

of them have suffered from methodological problems that limit the confidence that can be placed in their conclusions.

The results of more recent, more carefully controlled studies, which I will share with you shortly, have provided important new data in this area.

It is surprising to many people that the majority of women who seek breast augmentation are in middle adulthood, married and have children. This contradicts the frequently assumed stereotype of candidates for cosmetic breast enlargement.

The preoperative psychological status of these women has been studied through both clinical interviews and formal psychometric assessments. Clinical interview investigations have generally suggested a high degree of psychopathology in breast augmentation patients. However, these investigations have a number of methodological shortcomings which raise serious questions about their validity.

In contrast, studies that have used standardized psychometric tests generally have found

little evidence of psychopathology in these women. Only one study has found greater symptoms of depression in breast augmentation candidates as compared to controls.

The methodologies used in some of these psychometric studies also have limitations.

Intuitively many women seek breast augmentation surgery because they are not satisfied with the appearance of their bodies and their breasts. While such concerns were often dismissed as trivial vanity years ago, research over the past several decades has demonstrated the importance of appearance in everyday life. Not only are more physically attractive individuals perceived more favorably than those who are less attractive. It also appears that more attractive individuals receive preferential social treatment in both interpersonal and social situations.

Given this knowledge, improving one's appearance can be seen less as trivial vanity and more as a positive, health self-care strategy. This research, however, only explains the outside view of

physical appearance. It does not account for the inside view the way a person views his or her own appearance.

This internal perspective of physical appearance can be understood through the psychological construct of body image which encompasses an individual's perceptions, thoughts, feelings and behaviors about the body. Body image, particularly body image dissatisfaction, may be the most relevant construct by which to understand the motivation of cosmetic augmentation candidates.

Body image dissatisfaction is so prevalent in our society that researchers have labeled a normative discontent. One recent body image survey suggests that 56 percent of American women report dissatisfaction with their overall appearance, and 34 percent report a dissatisfaction with their breast size.

Furthermore, body dissatisfaction in women appears to have increased over the past several decades, suggesting that the recent occupational, economic, and political advances of women in this

country have not helped improve their personal body images.

My colleagues and I were the first to empirically assess body image dissatisfaction in prospective cosmetic surgery patients. Across several studies, we found that women who seek cosmetic surgery as compared to women who do not seek surgery report greater body imagine dissatisfaction with the specific body feature for which they are seeking surgery.

We have also completed three studies of breast augmentation patients. These studies have replicated our previous findings, suggesting that women who seek augmentation as compared, again, to women who do not seek surgery report greater dissatisfaction with their breasts.

These studies have also provided more specific information on the nature of this dissatisfaction. For example, more than 50 percent of augmentation patients reported that they avoided an undressing in front of others and that they camouflaged their preoperative breast appearance with special brassiere or clothing.

These upsetting experiences appear to have a negative effect on self-esteem. In the most recent investigation from our group, women who sought breast augmentation reported more appearance related teasing and a greater use of psychotherapy than did controls. These results may suggest that a history of appearance related teasing may be another variable that distinguishes women who do and do not seek breast augmentation.

Further, the greater use of psychotherapy in these women suggest that they may be experiencing negative emotional consequences as a result of their breast dissatisfaction.

Studies of the psychological consequences of breast augmentation have been largely anecdotal, though the reported satisfaction rates, as we already heard today, are encouragingly high. In the absence of physical complications of surgery, interview investigations have reported that the majority of women experience psychological benefits, including improvements in body image and self-esteem following augmentation surgery.

Two recent studies have provided even more convincing evidence of the psychological benefits of cosmetic surgery. Results from the first study found that as compared to preoperative levels, cosmetic surgery of patients reported significant improvements in depressive symptoms and quality of life six months after surgery.

Results from a preliminary investigation have found similar improvements in body image, also six months postoperatively. Thus, there is now growing evidence to suggest that cosmetic surgery, such as breast augmentation, leads to improvement in at least three areas of psychological functioning: body image, quality of life, and depressive symptoms.

A recent investigation of women who had their silicone breast implants removed further underscores the psychological impact of an altered body image. Women who had their implants removed reported less satisfaction with their appearance, fewer positive appearance related thoughts, and greater discrepancy between their ideal and post explantation breast size.

Thus, it appears that removal of a breast implant, something which has occurred more frequently as a result of prior controversies over silicone safety, may have a profound effect, negative effects, on psychological functioning.

In conclusion, recent evidence supports the view that women seek breast augmentation to reduce or eliminate their personal dissatisfaction with the size and shape of their breasts. Based on what we know of the importance of physical appearance in our society, this desire should not be viewed as a manifestation of psychopathology, but as a positive mechanism for improving one's appearance and body image.

Two recent studies suggest that cosmetic surgeries, such as breast augmentation, result in measurable improvements in body image, as well as depressive symptoms and quality of life. Given that the benefits of breast augmentation surgery are more in the psychological than physical realm, more research demonstrating the psychological benefits of the procedure is clearly warranted.

However, based on the current studies, it is reasonable to assume that the vast majority of women who choose breast augmentation surgery will enjoy significant psychological benefits that would otherwise be unavailable to them.

Thank you.

CHAIRMAN WHALEN: Thank you.

I think the get the award for the best timing today because the last word was right when the red light came on.

DR. SARWER: Yeah, but I also had that slip of the tongue at the beginning.

CHAIRMAN WHALEN: Are there any questions for Dr. Sarwer?

(No response.)

CHAIRMAN WHALEN: Just so the three remaining individuals who are going to be talking to us know, we will be getting to them in time.

We have one remaining consumer group to hear from. Dr. Blais, Pierre Blais is from the Chemically Associated Neurological Disorders, and in view of Ms. Stansell's yielding of half of her time,

would the timer please be set for 15 minutes?

DR. BLAIS: Thank you very much.

I differ from the other speakers inasmuch as I am not a U.S. citizen. I'm here on invitation. I'm not a member of the association, nor, for that matter, of any advocacy association.

I do not derive income from the breast implant trades, neither through implantation, explantation, health care, diagnostic, marketing, sale, or whatever.

I am here at my own expense. I have never received funding from any source with respect to this program.

I'm a former Canadian official with a position very similar to our colleagues here from the FDA. I had a similar role in Canada. I'm responsible for what may be the largest breast implant or, for that matter, general deep, long term implant study ever taken worldwide. It has lasted now 25 years to this day.

**

The part I wish to report today is a very small segment of this study. It concerns 250

specimens from a very large cohort of explanted devices collected between about 1989 to almost the present. Out of these, there were only a few that were suitable for the type of study according to our protocol.

The type of protocol that we had targeted was one where we would look for contamination in implants that had not failed. This is a minority of implants that are removed, and they also included a review of the mechanical issues surrounding the fabrication of implants.

We have heard today about many things. We have heard about how beneficial the implants can be psychologically, how beneficial they will be to cancer patients, the fact that they are liked by individuals who have had deformity and so on. This may be so I could agree with it. I applaud the studies. They're very worthwhile.

My interests, however, are much more mundane. I'm a scientist, and I'm also a technologist. I've studied those devices now for far in excess of 25 years. I go back to the '60s, and I

have personal direct recollection from the Joseph Kennedy hearings. Those of you who are my age will remember that.

Now, what I wish to impress on you is that the mention of science in the study, the retrospective study is one thing, and that may be so, but the mention of science in the context of fabrication and engineering of the implant is not here. I have never seen any evidence of intelligent engineering or science in the design, the fabrication or, for that matter, the post explantation analysis of these devices. They are articles of commerce of very low grade. They belong to technology. They do not belong to science.

Those of you who still hold the view that these things are scientific need only look at a few. I have some here. I won't bore you with that they are like, except to mention the part that I wish to draw attention to.

Virtually anything we have pulled out of patients over the last years that have not been outright broken amongst the salines were all septic,

septic to a level which is unprecedented in studies on scientific implants. They were visibly contaminated with all types of flora, something that by itself should be a sobering thought for any physician who puts them in and who takes them out.

What I want to draw your attention to is a very small segment of our study which has concerned saline implants. Two hundred and forty-two implants that fall into a certain category, a subclass of saline implants, 74 that fulfill criteria of being "intact" in the surgical sense of the word, six of the users reporting problems prior to removal, such as deflation, a few of them claiming systemic complications -- I'm not competent to discuss it -- three users only involved in litigation.

Out of these 74, 12 were very old implants, what we call the Jenny Mark I, which is a unique implant introduced in 1968 with a very coarse and, by the way, highly secure valve system. These are the ones that habitually are removed without rupture. It's an interesting observation.

The others, 62 of them, bearing the same

type of valve, this is what we call a forward valve or an apex valve. Those of you familiar with the trade will know what this symbols is. It is simply a hole with a diaphragm at the bottom and a plug at the top to cap it.

The early ones, the Jenny, were quite secure. The second generation which was introduced in '76 is not, nor is it designed to be, as best as I can figure out. This type of implant is designed to leak intentionally to support a claim of control of contracture. It is by itself an engineering misrepresentation. It is not a single product. It is made by nearly everyone in the trade. More than 18 different manufacturers have made it. The values all share the same process, the same problem because they all come from the same place. They are a commodity. They are an article of commerce marketed by a single manufacturer, sold to others.

Now, the other part of importance in this sub-study is that not only were the values of this design not terribly good in terms of manufacturing, but they did not even fit. The parts were not mated

correctly. To put it in very vulgar terms, it was like having a cork on a wine bottle which is about five millimeters smaller than the hole, so that if you put the cork in the bottle, it falls to the bottom.

Now, I ask you as a technologist, as a scientist, as a physician, as an administrator, as a layman, as a user, what would you think of a company that presents to you with an elaborate pre-market submission claiming elaborate studies and good science and good engineering, who cannot manufacture an object to the right dimensions? What credibility will the PMA have?

Now, there are many things. I've made a formal submission, and I'm very grateful to Dr. Krause for accepting it. It will be given to you.

Unlike many others, it involves 20 recommendations on what the committee has no option but to consider if they ever find that one of the submissions complies with the terms of the requirement. I'm not saying there are any. I have yet to find one, but there could be one.

If such an implant ever appears in your

files and you're required to give it assent as an approved product, then you have no option but to consider implementing the 20 recommendations that are made there, and many of them are quite surprising. They're also very old because the same recommendations are culled out of meetings that took place incidental to classification panels in 1978 right through to about 1983 and were reiterated again in the late '80s when the gel implant issue arose.

I'll just point to a few of them. If you wish to have further elaborations, I can do that personally, if an invitation.

One of the main issues that I have is that the FDA must address retrospectively warnings for users of the implants. They are exposed to risks which have never been made clear to them and have been denied. Yet they are undeniable in the light of laboratory findings.

The other issues have to do with disclosure and the clearing up of issues that are called possibilities, remote risks as opposed to inevitable, time dependent certainties.

These implants are literally replete with certainties. They are not probabilities.

And then finally I have to deal with the issue of breast feeding. In the light of any reasonable person who is briefed about breast physiology and in the light of the laboratory findings that we are getting from saline implant, there is no basis in any science, any technology, not even in psychology, that would justify breast feeding, and as surprising as it sounds, it has nothing to do with the offspring. It has to do with the very principle on why implants are put in in the first place.

If you attempt breast feeding with an implant, you will have a good chance of bringing the breast back to its pre-implantation condition, breast involution. It's all over medical texts.

The issue of the so-called selfishly oriented recommendation against breast feeding is absolute. It is a cosmetic issue and also one of risk.

Now, the issue of the offspring is secondary, but it's just as important in the ethical

sense because we now have implants that are not secure in terms of integrity, which are known to be colonized by a broad range of microorganisms which have access to the breast, and the breast is fully engorged and responsible for distribution of milk precursor product to the implant.

Therefore, the implant constitutes a direct channel for transmission of an infective vector to the offspring. This concept is so old that you will find it in European texts in 1965.

Contrary to opinions expressed this morning, the saline implant is not a 1968 discovery. It's a 1960 discovery, and to make it even more embarrassing, it's a Canadian one at that. It is my Breton who has foisted this on you. It is older than the gel implant. It's been known since the beginning that they constituted a microbiological hazard that would preclude absolutely any recommendation for breast feeding.

Finally, to conserve and try to establish a record of being timely, the issue of radiography must also be addressed. It is also transparently

obvious these devices, the very shell is structured and is radiopaque. As such, the uniqueness of the shell, its structure and its peculiarities, preclude any form of meaningful radiodiagnostic oncology aspect. The implant is not just a confusing factor. It is capable of generating both false positive and false negatives. Therefore, there should be an FDA recommendation with respect to deemphasizing any value of radiographic assessment for tumors.

Then last of all, I have the issue of cost. How and why did Canada governments become interested in breast implants? It had nothing to do with the health of the user, the offspring, the safety, or the cosmetic aspects, what we call efficacy. It had to do with cost.

Some of you know that Canada operates under a medicare system. In the early days of this debate, which is the late '70s, I performed a study on health care cost, which is easy to do. It's only a computer issue in Canada, as we have the record, and a very strong outcome came.

Anyone implanted consumed four times our

health care resources of a corresponded age adjusted individual. I haven't done the study since. I'm scared.

Now, this has enormous implications. If you do a macroeconomic analysis of this phenomenon, you will observe that both primary and secondary health care costs of some states and incidental to Medicare/Medicaid, which does operate in some states, you find that it exceeds in some cases the actual promotion studies, the cost of promoting the technology.

Now, as a result of this, everyone, whether or not they have implants, are affected. They are affected in the sense that third party insurers, HMOs, and everyone else who is in the health care funding business is looking at breast implants with much concern for good reasons, because they attract health care procedures,a nd they attract health care costs.

One doesn't have to be the rocket scientist to figure this out.

Finally, the issue, the last issue, I made

a small omission in disclosing conflict. It may not be a conflict. I have consulted for everybody, the breast implant industry, the breast implant professionals, the attorneys for defense, attorneys for plaintiffs, third party insurers, governments, you name it. I have done it, but I have not derived a living from it.

And finally, I do have an involvement as a witness, and it's a witness in Canada called a material witness incidental to a criminal investigation of the Canadian government surrounding wrongdoings in the approval process of medical devices.

Thank you very much.

CHAIRMAN WHALEN: Dr. Burkhardt

DR. BURKHARDT: Is it Dr. Blais?

DR. BLAIS: Yes, it is, sir.

DR. BURKHARDT: Thank you.

A couple of things that I couldn't understand. I'm just a little dense about this stuff, the thing that you said. You said that you had removed 74 intact saline implants.

DR. BLAIS: They're out of a group --

DR. BURKHARDT: I'm not finished yet.

DR. BLAIS: I'm sorry. I apologize.

DR. BURKHARDT: You removed 74 intact implants. Then you commented that the valve looked like it had been made to leak, and I don't understand whether the implants you removed were intact or deflated or what. What was the relationship there?

DR. BLAIS: They were intact in the sense of the word that you would use in your own operative report, Dr. Burkhardt.

DR. BURKHARDT: But were they deflated?

DR. BLAIS: They were fully inflated. Many of them were even over inflated.

DR. BURKHARDT: So they had not leaked.

DR. BLAIS: Correct. However, this is not true --

DR. BURKHARDT: That was the answer to my question. I just wanted to understand that.

Now, in terms of transmitting an infected vector to the offspring, it's my understanding, and we have an expert here who might be able to help us, that

about 95 percent of lactating mother's milk is contaminated with staff epidermatis. It's a normal organism in the milk, and this is the predominant organism that is recovered from around implants.

So it's not clear to me why you think that the implant itself is a vector in transmitting that.

DR. BLAIS: Yes, it's three questions actually that you have directed, and I'm familiar with the microbiology of the breast. In fact, it's not limited to stapholocci. It includes also propioni bactiacne and many other things, the natural flora of the contaminated functional breast.

However, the organisms in those implants were not of this genus. They belonged to the mycobacteria family for reasons I can't go into, but now I show you the diagram of this valve again, and I tell you that it is not secure.

Even though the implants were inflated, which puzzled us for a time, our modeling studies showed that the valve functioned as a pump. It would take extracellular fluid occupying the intracapsular space and through the user's habitual movements, this

would produce cyclic compression, and it drive fluid within the implant.

Therefore, the implant leaked not just one way,b ut in both directions and --

DR. BURKHARDT: Thank you very much.

DR. BLAIS: -- therefore, whatever is in would get out into the breast.

DR. BURKHARDT: Thank you.

DR. BLAIS: Thank you.

CHAIRMAN WHALEN: Yes, Dr. Dubler.

MS. DUBLER: On the very last page of your handout, you have a comment on publication.

DR. BLAIS: Yes.

MS. DUBLER: And how difficult it is to get these sorts of negative data published.

DR. BLAIS: Yes.

MS. DUBLER: Has the government of Canada -- has your report in any way been submitted formally and accepted by any agency of the Canadian government?

DR. BLAIS: No, Doctor. The report that you have in your hand was finished yesterday. You are privileged to have its first copy, or either cursed

with having its first copy.

MS. DUBLER: Thank you.

DR. BLAIS: I have published many things. I have not and deliberately avoided publication in this area as it has been painfully difficult to collect clinical material, and that could be the object of another presentation, but it has no place here.

CHAIRMAN WHALEN: Thank you.

We have three remaining individual consumers who were segregated into this separate area this morning due to some time constraints.

First, Ms. Diane Griffith.

And these are five minute presentations, please.

MS. GRIFFITH: Mine may go about five and a half. I hope you'll bear with me. I timed this the best I could.

Well, let's see. My name is Diane Griffith, and my travel has not been paid by anyone else. I'm not Social Security disability and that's my source of income.

I have no financial ties with any organization. I am a party to the Dow Chemical/Dow Corning lawsuit, and I don't perform surgical procedures.

I'm making a statement on behalf of Dr. Arthur C. Sehalski (phonetic) of the University of Southern Illinois. He's a scientist, an immunologist and could not be with us this afternoon.

The statement is confined to issues of the structural integrity within the human body of the shell of prothesis known as silicone gel breast implants and saline filled breast implants.

The statements quoted during the next five minutes come from two sources, namely, one, the 1999 National Academy press publication titled "Safety of Silicone Breast Implants," and, two, the 1999 published, peer reviewed paper by Dr. Eugene P. Goldberg and co-authors, titled "Silicone Gel Breast Implant Failure and Frequency of Additional Surgeries."

Analysis of 35 studies reporting examination of more than 8,000 explants. In the

executive summary of the Institute of Medicine's 1999 publication, the following statement appears in the second paragraph of page 3. "Precise frequencies of the rupture of gel filled or the deflation of saline filled implants are not available. The properties of these devices can affect rupture or deflation and have changed markedly over time, and particularly in the case of gel implants. It has not been possible to reliably diagnose and study rupture in an unbiased cross-section of implanted women."

Continuing, "rupture frequencies in the past have been considerable, and the rupture rate of current models has yet to be measured over the relevant periods of time."

Assuming the accuracy of the statement, of the sentence just quoted, and given the absence since this statement by the IOM committee was made of evidence to the contrary, why is the advisory committee even now considering a pre-market approval application for saline inflatable breast prosthesis.

It is not the labeling information available to the prospective saline implant recipient

that establishes or certifies safety. Labeling information merely informs the prospective recipient of risks. What it does not do and cannot do is provide substantial human based evidence on the duration of the integrity of the sell within women. Is this not obvious?

Are saline inflatable breast implanted women again to serve as a test population to determine safety, to determine rate of rupture? Doesn't the evidence from the studies conducted at the University of Florida's Biomaterials Center and the Tampa Bay Cranial-Facial and Plastic Surgery Center show a direct and suitable, significant correlation of implant duration with percent shell failure?

And don't the studies of Goldberg and co-workers credibly reveal a failure rate of 30 percent at five years, 50 percent at ten years, and 70 percent at 17 years?

In 1993, the AMA Council on Scientific Affairs suggested that the shell failure rate was four to six percent, and is this not true that the FDA itself has stated that five percent rupture is "not a

safety standard that the FDA can accept"? Has the FDA now changed its mind?

We would hope not.

Thank you.

CHAIRMAN WHALEN: Thank you.

Next is Dr. Anne Kasper.

DR. KASPER: My name is Anne Kasper, and I've been an advocate social science researcher and public policy expert in women's health for more than 25 years. I'm currently a senior research scientist with the Center for Research on Women and Gender at the University of Illinois at Chicago, which is a national center of excellence in women's health.

I've conducted two studies of women with breast cancer, the most recent study completed in May of '99 and supported by the U.S. Agency for Health Care Research and Quality.

I'm the co-editor of a book on breast cancer forthcoming later this year.

I've not received any travel money nor do I have financial ties with any industry or health society, and I am not associated with any implant

lawsuits, nor do I derive income from implants in any way.

I'm pleased to present testimony to you today and thank you for the opportunity to do so. The focus of my testimony will be on women's perceptions of the safety of breast implants following mastectomy and the importance or lack of importance breast implants have in their recovery from breast cancer.

In my testimony I draw on the experiences of 53 women who participated in the two qualitative research studies for which I was the principal investigator.

Most of these women diagnosed with breast cancer had a choice of treatment between lumpectomy with radiation and mastectomy. Although since 1985 we have known that the science has demonstrated equal survival with these two forms of treatment, individual women have their preferences.

Many of the women in my studies chose mastectomy for several reasons. One, they feared that lumpectomy would leave cancer remaining in the breast.

Two, they were afraid of the long term

effects of radiation.

Most important, however, their choice of mastectomy was made possible by the availability of breast implants and the assurances given them by their physicians.

The women were assured by their physicians that breast implants are safe and effective. Indeed, if any of the women had known at the time that neither silicone gel implants nor saline breast implants have never been approved by the FDA as safe and effective, they would be astonished.

As these women weighed their choices between lumpectomy and mastectomy, the issue of safety and effectiveness of implants did not enter their equations. Rather, like most Americans, they trusted their doctors, and they assumed that some independent authority had tested and approved the devices their doctors would assert in their chests.

In some, the belief that implants were safe and effective made the choice to undergo a mastectomy possible for most of these women. Without this belief, I contend that few of the women would

have had mastectomies, and their treatment choices would have been severely limited.

In a paper published in a peer reviewed journal, I discuss the effects of breast loss and breast reconstruction for the women in the earlier of the two studies. The women in this study stated that their physicians promoted breast reconstruction as important to the women's recovery from breast cancer and to a renewed sense of well-being.

A majority of the women who underwent mastectomy chose implants because they hoped to replace the breast lost to cancer, wanted to erase the memory and reminder of cancer, and believed that reconstruction would make them feel whole and normal again.

However, when the women were able to reflect back on their experiences, the majority of them were not convinced that breast reconstruction had meet their hopes and expectations, nor the assurances of well-being promoted by their physicians. The women found that reconstruction did not erase the reality of cancer, nor did it assure their return to normalcy.

Neither did the implant replace the lost breast. Rather, the reconstructed breast was a physical approximation that had none of the sensory, sexual, or maternal capacities of the normal breast.

Many of the women sensed that the sole purpose of the implanted breast was for it to appear to be what it was not. Many of the women had a sense of deception, deceived by their doctors, by their own expectations, and by the implant itself.

Breast reconstruction with implants should remain a choice for all women who have lost a breast to cancer. However, the FDA has an opportunity to end another deception, that breast implants are safe and effective for women who have had breast cancer.

I urge this panel to not approve saline inflatable breast implants until appropriate studies have determined whether or not these implants are safe in the short and the long term for women who have had breast cancer.

Thank you.

(Applause.)

CHAIRMAN WHALEN: Thank you.

Are there any questions?

DR. BURKHARDT: Yes, I have a question. In terms of breast reconstruction not duplicating the real thing, we all know that's the case. Is that the reason for your recommendation that we don't approve --

DR. KASPER: No. I'm just telling you that the women had a lot of faith in their implants. They had great hope as to what the implants would be for them, and that they were not a perfect replacement was a disappointment to them. Even though many of them had been told by their doctors it wouldn't be perfect, it was for them, for many of them, it was far less than perfect.

And the point I think I was trying to make was the risks associated with implants for many of them were not worth it because the satisfaction levels were not high.

DR. BURKHARDT: So is it your recommendation then that until the implants can be made more perfect we not approve them?

DR. KASPER: No. It's really more an

issue of safety and effectiveness. I mentioned that because this was what some of the women in my studies had told me about implants, and I think it simply behooves the FDA when dealing with women's lives to have the highest standard regardless of other issues, as well.

DR. BURKHARDT: Thank you.

DR. BANDEEN-ROCHE: I'm sorry. I think I just realized that I didn't quite put together everything that you said. At the end of your presentation, I thought I heard you say that implants should remain an option for women who had had their breast --

DR. KASPER: I breast reconstruction.

DR. BANDEEN-ROCHE: Breast reconstruction. Thank you.

DR. KASPER: Should remain an option, yes.

DR. BANDEEN-ROCHE: Thank you. Thank you.

CHAIRMAN WHALEN: Thank you, Dr. Kasper. Next we'll hear from Ms. Carol Sherman.

MS. SHERMAN: Hello. Although no less passionate about my statement, this should only take

about two minutes.

First, I'd like to thank you for listening to me today. I feel it's important for the panel to hear my very positive experience with the saline breast implant.

A little over a year ago I was diagnosed with early breast cancer. Within two weeks of the diagnosis I had a mastectomy and immediate reconstruction with a saline filled breast implant.

The emotional trauma of going from a totally health and fit person to someone who discovers they have this dreaded disease is overwhelming, to say the least. As you can imagine, there were many very emotional thoughts going through my mind, mostly having to do with am I going to live.

At the same time there was one good thing. I never had to envision myself with a deformity. I never even had to think about myself without a breast, not for one day.

I still remember my doctor's words. "But you can have immediate reconstruction and wake up from surgery with a breast." I took tremendous comfort in

those words, and I was informed of both the benefits and the risks at that time.

Most importantly, I was luck enough to be able to take comfort in the good news that my cancer was caught early. I thought to myself, as long as I'm healthy and free of the disease I don't care if one breast will be filled with a saline filled implant instead of breast tissue.

What I did care about was whatever the filler, I still had a breast. I was lucky enough to beat this disease. I didn't want a daily reminder. I didn't want to be ravaged with a missing breast. My self-esteem could not have handled that.

A very important part of surviving this kind of emotional trauma for me was to keep things as normal as possible, to bring normalcy back to my life as quickly as I could.

Within four weeks of my surgery, I put on a sports bra feeling comfortable and looking like I had perfectly normal breasts and went back to my regular and fairly rigorous workout schedule. From day one, I have had absolutely no problems with my

implant.

About a month later, I attended a special family event where comfortable and feeling good about my appearance, I was able to wear a favorite formal gown. Maybe four to six weeks after that, wearing another favorite stretch bathing suit to the pool was not even an issue for me. You couldn't tell that three months prior I had had a mastectomy because I had reconstruction with a saline filled implant.

I felt like me, normalcy. I know the most important part of my emotional recovery was returning to all of the theaters of my life in my normal way. Thank God I had this option. I had the option to feel whole, my body intact, with two breasts.

I don't even want to think about where I would be emotionally if I didn't have that option. It's a personal decision. I feel very strongly that all women like me should have the option to choose saline filled breast implants as long as they're fully informed of both the benefits and the risks. It's a matter of emotional health.

Thank you.

CHAIRMAN WHALEN: Thank you, Ms. Sherman.

Are you at all involved with any practice or company that is involved with putting these devices in?

MS. SHERMAN: No, I'm not.

CHAIRMAN WHALEN: Are you involved in any lawsuit that involves breast prosthesis?

MS. SHERMAN: No, I'm not.

CHAIRMAN WHALEN: Thank you.

That being done, we will now proceed with the presentation by Dr. Celia Witten, Director of the Division of General and Restorative Devices, to discuss the regulation of saline filled breast prostheses.

DR. WITTEN: Thank you. Thanks for your patience during my effort to enter the 21st Century.

Good afternoon. I'd like to welcome everyone to this meeting of the General and Plastic Surgical Devices Advisory Panel.

I'm Celia Witten, Division Director of the Division of General and Restorative Devices at the FDA.

Over the next few days, we will be asking you to provide us with your expert recommendations on three pre-market applications for saline filled breast implants.

You are also charged with the very important task of providing us with recommendations regarding the kind of information that is important to provide in patient labeling so that women can be adequately informed.

I'm going to provide some brief background information for today's meeting. I will summarize the regulatory history of saline filled breast implants and the events that bring us here today. I will summarize the types of information provided the sponsors to assist them in planning to collect the preclinical and clinical data needed to support a pre-market approval application.

This information is described in the draft breast implant guidance document. This document was originally provided in 1994 and most recently updated in 1999. The recent updated version incorporated the clinical study design elements that were highlighted

in the points to consider letter issued to industry in June of 1996, which I will also summarize briefly.

I will speak also about what we have learned from the literature since the time that these products were classified.

As has already been noted here today, saline breast implants have been on the market since before 1976. FDA classified these products as Class III products in 1988. Because these products were grandfathered as pre-amendments products, they were allowed to remain as marketed products until such time as FDA issued a rule calling for safety and effectiveness information. New products could enter the market via the 510(k) pathway during this time. Products could also be made available during investigational study.

When FDA issued a rule calling for safety and effectiveness information in a pre-market approval application, termed PMA, this regulatory status changed. FDA issued the call for submission of pre-market applications for the saline filled breast prosthesis on August 19th, 1999. The sponsors had 90

days from the time of that call to submit a PMA and have it filed.

All products need to have an approval of the pre-market application within 180 days of that call that was issued on August 19th in order to remain on the market. Thus, the review process for these pre-amendments products, which are already on the market at the time that safety and effectiveness data is called for, is different with respect to timing from the review of PMAs for novel products that are not yet on the market.

For pre-amendments products, there is limited time for interaction with sponsors during the review process prior to the panel meeting because of the 180-day time frame until products are either approved or off the market.

In addition to working interactively with sponsors prior to the call for PMAs, we continue to work with sponsors during the review process.

FDA has provided guidance both in written form and in discussions with sponsors to assist sponsors to develop the data needed to support a pre-

market application. The guidance document for these products that is available provides manufacturers with information regarding data to submit in several important areas.

In particular, the chemistry section describes -- suggests how to describe and characterize the device, and the toxicology section includes a description of the types of biocompatibility information that is necessary.

Mechanical testing as described in the type of clinical data need is also covered.

As I mentioned before, the current guidance document is a revision of an older version. The clinical portion has been incorporated -- has been updated to incorporate other information the FDA provided to sponsors. In particular, I want to note in 1996 the letter that FDA issued to sponsors and to industry that outlined essential elements of a clinical study of these products. It is worth highlighting some key points.

The FDA suggested a sample size adequate to determine the adverse event rate with reasonable

precision and suggested 500 women be followed to the end of the study. The suggested worst case precision within which to be able to describe the incidence of adverse events, such as deflation, was plus or minus four percent.

Separate augmentation and reconstruction cohorts were suggested because of the potentially different performance in those groups.

A two year minimum follow-up pre-market was suggested in that letter. It was also suggested that sponsors plan ten years' total follow-up, some of the follow-up to be performed post market. The letter suggested follow-up intervals, and in addition to the primary study endpoints, quality of life, and connective tissue disease screening were suggested.

Since 1988, when these products were originally classified, there have been a substantial number of public contributions to the scientific literature that have added to our knowledge of these products. Although there are a number of possible and actual types of complications described in the literature, I would like to touch briefly on two types

of complications, in particular: connective tissue disease and local complications and re-operations.

I would like to discuss what we have learned since 1988 these two subjects. There have been a number of epidemiologic studies investigating the potential contribution of these products to the development of connective tissue disease. It appears from the literature that there is no or at most a small increased risk of connective tissue disease from these products.

There are some limitations to the studies performed, however, and these include the heterogeneity of the products in most of the studies and the fact that some of these studies looked at classical connective tissue disease, but were not designed to assess a typical connective tissue disease.

We have also learned from the literature that the risk of local complications and re-operations for these products as a whole is not insignificant. Local complications can include deflation, contracture, infections, breast pain, and hematoma.

These complication rates are reported in the literature very widely. The FDA and DHHS commissioned a report by the Institute of Medicine on the safety of silicone breast implants based on information in published literature. The Institute of Medicine review included saline breast implants which have silicone elastomer shells. The Institute of Medicine report concluded that local and perioperative complications are the primary safety issue with silicone breast implants. This group in their report also noted a deficiency in the literature with respect to product specific information.

Over the next day and a half, you will be reviewing the product specific information that sponsors have provided in their PMAs. You will be asked to evaluate the information in each pre-market approval application and advise us as to whether there is sufficient information in each application to provide a reasonable assurance of safety and effectiveness.

You will be asked to make your recommendations based on data contained within the

PMAs and based on your scientific knowledge. You will be provided a list of questions for each PMA to consider as you review the data. Each application will be considered separately on its own merits.

We have heard this morning a number of comments from the public, and one of the themes that emerged is the important question about adequate informed consent from patients and how to make sure that patient consent is truly informed.

On Friday, we will seek your guidance on the important task of assessing what information we can provide to women to best assist them to make informed decision regarding breast implant surgery.

The FDA very much appreciates your giving of your time and expertise to accomplish this important task. And now I'm going to turn it back over to you, Dr. Whalen.

CHAIRMAN WHALEN: Thank you, Dr. Witten.

Does the panel have any questions for Dr. Witten?

(No response.)

CHAIRMAN WHALEN: Thank you very much.

DR. WITTEN: Thank you.

CHAIRMAN WHALEN: Next, Dr. Wendie Berg will discuss considerations of imaging patients with breast implants.

Dr. Berg.

DR. BERG: Thank you, Mr. Chairman, members of the panel.

If I can have the lights down a little bit, as a radiologist.

(Laughter.)

DR. BERG: Can I have the next slide, please?

I'm going to be presenting imaging considerations largely focusing on breast cancer diagnosis in women with breast implants. Rupture, particularly with saline implants, is really a clinical diagnosis.

Periprosthetic fluid is a common finding on imaging, but we dismissed this. It's not thought to represent leakage on the whole, and again, I'm going to focus my comments on detection of breast cancer.

Could I have the next slide, please?

We can argue about the specific number of women who have undergone breast implantation, but approximately two million women in the United States are affected by it, and again, most of my comments are going to be directed to women with augmentation rather than reconstruction since we do not generally image the breast after mastectomy.

If one considers the rate of breast cancer to be approximately one in nine over a course of a lifetime, we can estimate that roughly 200,000 women with breast implants will develop breast cancer.

Next slide, please.

Mammography remains the standard for early detection of breast cancer. The goal, of course, is to detect breast cancer before it becomes palpable at an earlier, more curable stage. We know from the literature that 90 to 95 percent cure rates are achievable when breast cancer is detected at Stage 0 or Stage 1, and this is nonpalpable disease, largely found by mammographic screening.

Survival rates and disease free survival,

in particular, drops to 60 to 70 percent when lymph nodes are involved by the tumor. That number further drops to approximately 40 percent when the lymph nodes are involved and the primary tumor is palpable at presentation.

Next slide, please.

There have been several studies looking at the risk of breast cancer in women with implants, and they have rather conclusively demonstrated to date that there is no increased risk of breast cancer as a result of the presence of the implant, and in fact, in several smaller studies there has been actually a slightly decreased rate of breast cancer compared to that expected.

May I have the next slide, please?

Some general considerations first, and then I'll get into specific data that is available.

The American College of Radiology Standards require the performance of routine views, as well as implant displaced views in order to adequately evaluate the breast tissue in patients with implants. As a result, we can expect at least double the

radiation dose to the breast tissue per mammogram obtained in such patients.

Further, the presence of implants in and of themselves is an indication for diagnostic mammography, which would allow the mammograms to be reviewed by the radiologist when the patient is there in the suite. The reason for this is that many times the technologist is unable to obtain an optimal mammogram at the first pass, and additional views would be needed to adequately compress or evaluate the breast tissue.

As a result, we again anticipate at least more than double the cost of annual surveillance mammography.

Next slide, please.

These are rather difficult to project, but just to illustrate, this is a mammography with routine views first in a patient with silicone implants, and the next slide, please. The corresponding images are obtained when the implant is pushed back out of the field of view, allowing better compression of the implant -- of the parenchyma itself.

Next slide, please.

Even with such techniques, there is a reduction in the visualized breast tissue in patients who have breast implants. It's difficult to answer absolutely how much that reduction would be in any given patient. There is some data from a series where patients' mammograms were measured both prior to and after implantation, and overall it was found that 30 percent reduction in the visualized breast parenchyma in the absence of any contracture.

If contracture is present, it's more difficult to compress the breast. As a result, greater reduction, on the order of 50 percent, was observed in the amount of visualized parenchyma. Even with implant displacement techniques, the amount of breast tissue that we see is still decreased compared to a patient without implants, and in fact, on average that was 25 percent still obscured with implant displacement; greater, on the order of 35 percent, if the implants are subglandular compare to subpectoral locations.

Next slide, please.

To illustrate, this is a woman who had silicone implant placed behind the muscle and there's very little breast tissue visible on the routine views.

Next slide please.

And this is difficult to project, but on the implant displaced views, a subtle cluster of calcifications was noted, and it's actually right here in the middle of a spot magnification view. This patient had a very small focus of ductile carcinoma in situ that was detected despite the presence of the implants.

Next slide, please.

However, it's not always so easy to displace the implant. This woman has a saline implant, and you can see that it's still quite dense, although you can see a little bit of the internal structure and the folds of the edge of the implant.

And despite every attempt at implant displacement, this is the best mammogram that could be obtained. She had very little breast tissue.

Next slide, please.

She underwent an ultrasound. I don't know if we can have the lights down any further -- underwent an ultrasound that showed the implant itself, and there was a very subtle mass anterior to the implant that was an early infiltrating ductile carcinoma, completely invisible on mammography as a result of the implant.

Next slide, please.

In general, as I've mentioned, the implant can hide the breast tissue directly and, as a result, can hide lesions as well in the breast tissue. Adequate compression is sometimes difficult to achieve due to contracture, pain, and the mass effect of the implant itself. It can displace the tissue and cause overlap in the normal parenchyma.

It can be difficult to visualize lesions in both projections. You might see that lesion inferiorally in the breast, and yet it's hidden by the implant in the craniocaudal projection, despite implant displacement techniques, and this can confound interpretation as well as limit the biopsy options and make it more difficult to biopsy any lesions that are

seen.

And finally, in the woman who had undergone removal of an implant, there can be extensive scarring, not always, but there can be. That can confound interpretation. There can be residual calcifications, particularly if the capsule is left behind after removal of the implant, and both of these can mimic cancer.

Next slide, please.

To illustrate, again, this is a patient who has a silicone implant behind the breast tissue, and this was the best mammogram that could be obtained. Very poor compression was achieved in the tissue itself, and you can see there's a rather large density. This is approximately four centimeter invasive ductile carcinoma was visible, but if there were any other lesions in this breast, it would be very difficult to assess that.

Next slide, please.

And, again, this doesn't project well in this lighting, but this was a patient who was found to have a subtle cluster of calcifications in the

inferior breast.

Next slide, please.

But she had ruptured saline implants bilaterally, and we were unable to localize the calcifications in the other plane because they really proved to be on the inferior breast directly underneath the implant. We were able to biopsy these with stereotactic technique and found fibrocystic change in this case.

Next slide, please.

After implant removal we can see a variety of changes that are very suspicious. This particular patient had explantation of an intact saline implant, but remained with a spiculated density at the chest wall which, if you didn't know the history, would be considered highly suspicious.

She then underwent ultrasound -- next slide, please -- and was found to have a seroma.

Next slide, please.

Another patient who had undergone explantation, again, had a spiculated density of the chest wall, and there were actually calcifications

evident within this, a lot of deformity in the breast tissue, difficult to get an adequate mammogram, especially in the inferior breast.

This proved to be an infective collection. We're having fund. I think you need a few more microphones.

Next slide, please.

I mentioned that the capsule itself can cause some problems with interpretation, and the main reason for that is the presence of calcifications in the capsule itself, a rather common finding. Judy Distouet and colleagues found about a quarter of the patients have some degree of calcification in the capsule. Usually it's relatively easy to identify because it's relatively coarse and typically benign, but when it's first starting it can, again, mimic early cancer.

Next slide, please.

Just an illustration of these calcified capsules. You can see it really can get quite extensive. This patient had severe contracture, as well.

Next slide, please.

And the calcification in that capsule can be visible, easily distinguished from ligament calcification or not. If it's left behind, this capsule itself can form the pocket for collecting fluid, and as I mentioned that one case, infection.

Next slide, please.

I think the overwhelming question which I was asked to address is really will the diagnosis of breast cancer be delayed in women with implants as a result of suboptimal mammography. Unfortunately I'm not sure I can answer this question. There are only several small, retrospective studies that have been performed which are really inadequate to answer this question at this time.

Next slide, please.

I'm going to present a literature review, but there is, again, minimal data and keep in mind most serious report results from silicone implants, not saline.

Next slide.

I think there is some evidence to suggest,

however, that the results may be generalizable between silicone and saline implants. A study again from Washington University in 1989, using the American College of Radiology and Mammography Phantom, which includes a variety of artifacts, including dense specks, which mimic calcifications, and densities which mimic early cancerous manifests as masses, was used with a variety of types of implants positioned on top of the Phantom and a normal mammography exposure performed.

In their study, they found the shell alone minimally altered the ability to detect the various artifacts, but the shell filled with either silicone or saline completely obscured all artifacts.

Next slide, please.

What kind of performance are we expecting from mammography? Well, this is a good question. I'm not sure we have the absolute answer, but in the American Health Care Policy Research Manual from 1994, we do have benchmarks that were established by a variety of experts in the field suggesting that with routine screening, we should be able to achieve

detecting of the majority of cancers at Stage 0 or Stage 1, over 50 percent, and that node positivity should be under 25 percent of the patients diagnosed, and overall sensitivity of mammography on the order of 85 percent should be achievable.

I think that last number may be a little optimistic. There have been multiple studies showing performance. In practice it's closer to 78 to 80 percent detection of breast cancer, allowing for a variety of factors, including errors in interpretation.

Next slide, please.

These are the references on which I have drawn, the literature that does exist on implants and breast cancer detection.

Next slide, please.

There's a lot of information here, but just to summarize, you can see across these studies very small numbers of patients, and I think these are patients who had augmented breasts with usually silicone implants and were not undergoing annual mammographic screening. So this is simply at the time

of detection looking at results.

They had ten patients, six patients, seven who had implant displacement views, as well as routine views, a total of 41 patients in the study of Silverstein, but all small numbers of patients in these studies.

Overall, the degree to which cancers were visible mammographically ranged from 55 percent up to a high of 86 percent. Overall palpability of the lesions detected was quite high across all these series. The lowest was the first study here with Leibman and Kruse, where six out of ten cancers were palpable at presentation, but the vast majority of the cancers in these studies were palpable, and again, this may reflect the lack of routine screening in these patients.

Nodal positivity was also higher than that benchmark of 25 percent across most of these series. One study in particular I want to call your attention to was that of Laurie Fajardo and colleagues done at Arizona. At the time 18 patients all had implant displaced mammography views, as well as routine views,

and in that series the sensitivity was only 67 percent, and in fact, 39 percent had positive lymph nodes at presentation.

Next slide, please.

So to summarize, the majority of patients in these studies that have been done to date had only routine mammographic views without implant displacement, and we've already shown, I think, that it's mandatory that the implant displacement views be obtained in order to adequately evaluate the parenchyma.

More cancers were palpable at diagnosis than in general. We expect that number to be about 40 percent palpable at presentation. In these series it was from 80 to 90 percent in the majority of the studies.

The stage distribution of cancers, however, in the papers that had control groups was not found to be significantly different in women with implants, nor was the survival found to be different.

Okay. Next slide, please.

Overall, where it could be assessed, 66